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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,591	12/04/2001	Franco Castellini	BUG 2 0150	5163

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

cb9

Office Action Summary

Application No.

10/004,591

Applicant(s)

CASTELLINI, FRANCO

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-29, 42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7, 10-20, 23, 25-27, 42 and 43 is/are rejected.
- 7) ☒ Claim(s) 8, 9, 21, 22, 24, 28, 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 2-4, 6, 7, 10-20, 23, 25-27, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banks et al.(EP 0 531 067) or Siebel et al.(US 4,912,332) in view of Fitton (US 6,106,771) and taken further in view of Tuompo et al.(US 5,910,420).

The reference of Banks et al. discloses a device for detecting the presence of biofilm on the surfaces of conduits. The device includes a light emitter (34) and detector (18).

The reference of Siebel et al. discloses a device for detecting the presence of biofilm on the surfaces of conduits. The device includes a light emitter (5) and detector (11).

While the references disclose using the device for conduits in process streams, the reference is silent as to the use of the device on a conduit of a dental unit.

The reference of Fitton discloses that scale and biofilms are a concern in the waterlines of dental units (See the entire disclosure).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the detection system of the reference of Banks et al. or Siebel et al. in a conduit of a dental unit for the known and expected result of providing a means recognized in the art for

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detecting biofilms in conduits which is a concern in the waterlines of dental units as evidenced by the reference of Fitton.

With respect to claims 42 and 43, the above claims differ by reciting that the system includes structure for introducing a reagent with reacts with the biofilm to be detected.

The reference Tuompo et al. discloses that the use of chemical reagents with biofilms form on the surface of a conduit is known in the art (See column 2, lines 11-42).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a chemical reagent in the system of the modified primary references for the known and expected result of providing an alternative means recognized in the art to achieve the same result. Use of chemical reagents with respect the optical detectors of the primary references would allow one of ordinary skill in the art to distinguish biological films from other films such as scale.

When using chemical reagents as suggested above, it would have been obvious to one of ordinary skill in the art to determine the optimum wavelength of light to employ based merely on the specifics of the reagent employed while allowing the color to be detected by the optical detection system. With respect to the use of a control signal, the use of control signals is known in the art for subtracting background noise and/or calibration of the detection signal.

With respect to the use of a means for dispensing reagent, it would have been obvious to one of ordinary skill in the art to provide a means for adding reagent (inlet port and reagent reservoir, pump, etc.) for the known and expected result of providing the reagent within the conduit which is required of the test suggested by the reference of Tuompo et al.

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With respect to the use of an electrical properties detector, the reference of Tuompo et al. also discloses that electric conductivity is known in the art for the detection of biofilms (See column 2, lines 20-22).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ an electrical conductivity sensor in the waterlines on a dental unit for the known and expected result of providing an alternative means recognized in the art to achieve the same result, detection of biofilms on the surfaces of conduits. In the absence of a showing of criticality and/or unexpected results, the use of a resistance sensor or conductivity sensor would have been within the purview of one having ordinary skill in the art since one is merely a reciprocal of the other.

With respect to the presence of an altering means, the reference of Siebel et al. discloses that it is known in the art to provide a signal so as to trigger the addition of deposit removing means (See column 5, lines 27-31).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to determine the optimal triggering signal based merely on the means employed for removing the deposit. The use of audible or visual displace signals would have been obvious when the method of removal employs manual steps such as cleaning, adding reagents or replacing conduits.

With respect to the location of the detector with respect to the waterlines of the dental unit (claim 23), it would have been obvious to one of ordinary skill in the art to determine the optimal position while providing an indication of contamination. One of ordinary skill in the art would recognize that any water flow which comes into contact with the patient would be of

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concern with respect to contamination as opposed to fluids used to merely rinse a sink of the dental unit.

3. Claims 5, 25, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Banks et al.(EP 0 531 067) or Siebel et al.(US 4,912,332) in view of Fitton (US 6,106,771) and Tuompo et al.(US 5,910,420) taken further in view of Schapira et al.(US 5,249,874).

The combination of either Banks et al. or Siebel et al. with the references of Fitton and Tuompo et al. has been discussed above.

The above claims differ by reciting that the detector is a removable component.

The reference of Schapira et al. discloses a device for the detection of biofilms in a conduit that employs a removable element (19).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a detection device as disclosed by the reference of Schapira et al. in the system of the modified primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the same result, detection of a biofilm in dental unit conduit. Use of the Schapira et al. device would not require the use of any complex electronic components.

Note the test device includes a housing unit (7,3) that allows the test element to be positioned within the conduit while permitting normal flow of fluid through the conduit.

With respect to whether or not the housing unit is integral or disposable (removable), it is well established that whether an element is integral or separable is not a patentable distinction and is merely an obvious matter in design choice that it within the level of one having ordinary

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skill in the art (See *In re Larson*, 144 USPQ 347 (CCPA 1965) and *In re Dulberg*, 129 USPQ 348 (CCPA 1961)).

Allowable Subject Matter

4. Claims 8, 9, 21, 22, 24, 28 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 8, 9 and 21, while the prior art of record suggests adding reagent to the conduits to contact the biofilm, the prior art of record fails to teach or fairly suggest the combination of elements recited in these claims for allowing the test liquid to be remove, recirculated and/or isolated within a test portion of the dental unit conduit.

With respect to claim 22, the prior art of record fails to teach or fairly suggest that the conduit portion of the unit forms an extension of one of the conduits that supply the handpieces and is equipped with an independent drain.

With respect to claim 24, the prior art of record fails to teach or fairly suggest the use a plurality of balls of the same material as the test conduit as a sensing element for biofilms.

With respect to claims 28 and 29, the prior art of record fails to teach or fairly suggest a detection device which includes a plurality of balls and is constructed such that the balls can be removed one at a time and filled with a biofilm reagent such that the ball is contacted with a color changing reagent when removed from contact with the flow of fluid in the conduit.

Response to Arguments

6. Applicant's arguments filed 27 Aug. 2003 have been fully considered but they are not persuasive.

With respect to new claims 42 and 43, Applicants argue that the features of these claims are "not disclosed or suggested by Banks, Siebel, Fitton, Tuompo, or any combination thereof" for the following reasons.

i) The devices for detecting the presence of biofilm disclosed by the references of Banks and Siebel are not adapted to detect the reaction between the biofilm and the fluid reagent and would not be capable of detecting a reaction between a reagent and the biofilm.

ii) The reference of Tuompo does not teach to use the reagent fluid in order to detect the biofilm.

iii) Since the reference of Tuompo does not teach the use the fluid reagent for the detection of biofilm, it is not obvious to use the detecting device of Banks or Siebel to detect the reaction between the biofilm and the fluid.

In response to i) above, while the references of Banks and Siebel do not specifically disclose the use of a reagent to monitor the biofilm, the references have been cited to teach that it is known in the art to optically monitor a conduit for the presence of a biofilm. These references disclose the use of emitters and detectors to achieve this desired detection.

In response to ii) above, the Examiner is of the position that the reference of Tuompo et al. clearly discloses the use of a fluid reagent (dye) for the detection of biofilm (See column 2, lines 11-43). Note the dye "reacts" with the biofilm so as to optically label the biofilm.

In response to iii) above, since the reference of Tuompo et al. teaches the use of a fluid reagent (dye) to detect biofilms, it would have been obvious to one of ordinary skill in the art to modify the systems of either Banks or Siebel to employ a fluid reagent (dye) so as to facilitate the detection of biofilms. Note the reference of Tuompo et al. discloses that biofilms are not always visible, therefore, use of a reagent (dye) would allow detection of the biofilms that are not visible. Furthermore, the use of optical emitter and detectors are notoriously well known in the art for use with dye reactions. The optical wavelengths are chosen to be compatible with the dye employed and reduce any background conditions that may alter the optical result.

Note in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986):

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37


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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006 (after 12/16/2003 571-272-1269). The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920 (after 12/16/2003 571-272-1281). The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB